

REMARKS

Claims 1-3, 5, 7, 10-20, 22-27, and 29 are pending in the present application, of which Claims 1-3, 7, 10-20, 23-26, and 29 are under consideration. Claims 1, 11, 19, and 23 have been amended to clarify the invention. No new matter is presented by the present amendment, and no further search or consideration should be required. Entry of the present amendment and reconsideration of the application is therefore respectfully requested.

I. Rejection Under 35 U.S.C. § 103

Claims 1-4, 7, and 10-20

Claims 1-4, 7, and 10-20 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Van West in view of Sanchez and Lanza. Again, Applicants respectfully traverse this rejection for the reasons of record, and at least the reasons that follow.

Following on Applicants' previous arguments, the Office has maintained the rejection of the above claims over Van West in view of Sanchez and Lanza. In support of the rejection, the Office alleges that the use of "comprising" as a transition phrase "makes the claim inclusive, i.e. other components may be used in conjunction with the instantly claimed invention. Therefore, for the patient population who receive allograft therapy for the treatment of major depression, the motivation to treat using citalopram and ibuprofen, along with other compositions is obvious." *Office Action* mailed May 14, 2008 at page 4. The Office continues, stating that "any amount used in conjunction with allograft therapy can be construed an 'effective' amount to treat or alleviate depression" *Id.* Applicants respectfully disagree.

Initially, it is noted that the present claims, to the extent under consideration, now recite that the recited therapeutic methods consist essentially of the administration of the recited compositions or combinations of compositions. As such, other components and materially therapeutic method steps, i.e., allograft therapy, are excluded from the scope of the claims. For at least this additional reason, it is submitted that this rejection should be withdrawn.

In addition, in all instances, the therapeutic focus of the claimed methods include the administration of an anti-inflammatory agent where the anti-inflammatory agent is administered in an amount and for a purpose effective to treat or alleviate depression. Whatever else the cited references may disclose, there is no teaching or suggestion of the administration of an anti-inflammatory agent in an amount effective intended to treat or alleviate depression to a subject in need thereof. Contrary to the Office's allegation, the mere administration of ibuprofen in conjunction with the allograft therapy of Lanza does not equate to a teaching of an effective amount to treat or alleviate depression. Rather, the ibuprofen is administered in Lanza in an amount, and for the intended purpose, effective to achieve anti-inflammatory effects.

There simply is no rational underpinning to support a predictable expectation that ibuprofen would be useful in the treatment or alleviation of depression itself, or any predictable expectation as to the administration of an amount of ibuprofen to a subject in need thereof effective in this regard.

Thus, contrary to the Office's assertions, the ibuprofen of Lanza does not have the same utility for the same purpose as the compositions in Van West and/or Sanchez. Moreover, the allograft implantation techniques of Lanza are substantially different from the non-biological, non-invasive approaches of Van West and Sanchez. As such, those of skill in the art would not routinely look to combine the cell-based compositions of Lanza with the compositions of Van West and/or Sanchez.

For at least these reasons, withdrawal of the present rejection is respectfully requested.

Claims 23-26 and 28-29

Claims 23-26 and 28-29 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Anisman in view of Van West, Sanchez and Lanza. Applicants respectfully traverse this rejection for at least the reasons of record as well as the reasons that follow.

As discussed above, whatever else the cited references may disclose, there is no teaching or suggestion of the administration of an anti-inflammatory agent for the purpose and in an

amount effective to treat or alleviate depression to a subject in need thereof. The teachings in Anisman with regard to the impact and interaction of cytokines in the pathology of depression does nothing to remedy this deficiency. In fact, Anisman does not disclose or suggest the administration of anti-inflammatory agents to alleviate the depressive symptoms induced by the cytokine therapy. Rather, Anisman strictly focuses on traditional antidepressant therapy. As such, there is nothing to lead those of skill in the art to the presently claimed invention.

For at least these reasons, and the reasons discussed above, withdrawal of the present rejection is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, applicant respectfully requests withdrawal of the outstanding rejections and timely allowance of the pending claims. If the Examiner believes that a telephone conference would be useful in resolving any outstanding issues, he is encouraged to call applicant's undersigned representative at (303) 863-2303.

Respectfully submitted,

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